California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Edan Diagnostics – Patient Monitor (elite V5, V6, V8) Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
01/22/2026	EDAN elite V series patient monitors (elite V5, V6, V8) are bedside physiological monitoring devices used to continuously track vital signs such as ECG, SpO2, blood pressure, respiration, and temperature in clinical settings.	Edan Diagnostics San Diego, CA, USA	Potential cybersecurity vulnerabilities related to improper IP address configuration identified following an FDA It Has Come to Our Attention (IHCTOA) letter.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Lot Code:** N/A **Model No.:** elite V5, elite V6, elite V8 **UDI-DI:** **elite V5**: 06944413802155 **elite V6**: 06944413802162 **elite V8**: 06944413801707 **S/N range:** Multiple serial numbers (see full list in recall data)	342 Units; Nationwide including California (**elite V5**: 8 units in CA; **elite V6**: 3 units in CA; **elite V8**: 9 units in CA)	October 2025 and prior.

For additional information, please visit the FDA Website.